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GE Healthcare Inc. and General Electric Company

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

KIMBERLY GREMO,

Plaintiff,

-vs-

BAYER CORPORATION; BAYER HEALTHCARE LLC; BAYER HEALTHCARE PHARMACEUTICALS, INC.; GE HEALTHCARE, INC.; GENERAL ELECTRIC COMPANY; MALLINCKRODT, INC.; MALLINCKRODT LLC; GUERBERT LLC; LIEBEL-FLARSHEIM COMPANY LLC; AMERISOURCE BERGEN CORPORATION; AMERISOURCE BERGEN DRUG CORPORATION,

Defendants.

CIVIL ACTION NO. 19-13432 (NLH)(AMD)

DEFENDANTS GE HEALTHCARE INC. AND GENERAL ELECTRIC COMPANY'S MEMORANDUM IN SUPPORT OF THEIR MOTION TO DISMISS PLAINTIFF'S AMENDED COMPLAINT

Motion returnable: October 21, 2019

(Document Electronically Filed)

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Defendants General Electric Company and GE Healthcare Inc. (collectively "GEHC") respectfully submit this memorandum in support of their motion to dismiss Plaintiff's Amended Complaint pursuant to Federal Rules of Civil Procedure 8(a) and 12(b)(6).

INTRODUCTION

Plaintiff Kimberly Gremo filed her Amended Complaint while GEHC's motion to dismiss the initial Complaint was pending. Despite knowledge of GEHC's arguments, Plaintiff still has not complied with her pleading requirements. To the extent Plaintiff provides any detail of her claims, her allegations confirm her inadequate warnings claim is preempted. Other than this preempted claim, Plaintiff fails to allege sufficient facts regarding her alleged personal injuries and damages that arose from receiving Omniscan, GEHC's product. Only a few, limited statements in Plaintiff's Amended Complaint relate to GEHC specifically and Plaintiff's use of Omniscan.

Plaintiff's Amended Complaint identifies 10 MRI procedures over a ten-year period in which she received one of three gadolinium-based contrast agents ("GBCAs")—Omniscan, OptiMARK, and Magnevist. Am. Compl. ¶ 164. Based on these administrations, Plaintiff asserts three claims against eleven Defendants: (1) New Jersey Products Liability Act ("NJPLA"): failure to warn; (2) NJPLA: defective design; and (3) breach of express warranty. Am. Compl. ¶¶ 168-211. In

support of Plaintiff's claims against GEHC, Plaintiff alleges she received Omniscan in 2012, 2013, and 2016, and as a result, developed "Gadolinium Deposition Disease," which she alleges is "characterized by a multitude of symptoms and adverse health effects[.]" *Id.* at ¶ 166. Plaintiff alleges she was diagnosed by "her physician, Dr. Richard Semelka," *id.*, who is a radiologist.

As courts have recently recognized, Plaintiff's failure-to-warn claim are preempted under federal law. Food and Drug Administration has expressly determined that gadolinium has not been scientifically shown to cause any adverse effects in people like Plaintiff, who have normal kidney function. In 2017—a year after Plaintiff received Omniscan for the last time— FDA issued the following statement regarding gadolinium: "Gadolinium retention has not been directly linked to adverse health effects in patients with normal kidney function, and we have concluded that the benefit of all approved GBCAs continues to outweigh any potential risks."[1]

Even if preemption did not bar her claims, Plaintiff's remaining causes of action against GEHC are inadequately pled. Other than a few paragraphs, the entirety of Plaintiff's Amended Complaint is unrelated to Plaintiff, or to GEHC

[1] U.S. Food & Drug Administration, FDA Drug Safety Communication: FDA warns that gadolinium-based contrast agents (GBCAs) are retained in the body; requires new class warnings, Dec. 19, 2017, https://www.fda.gov/Drugs/DrugSafety/ucm589213.htm (last visited Sept. 10, 2019).

specifically. The Amended Complaint provides a recitation of the alleged history of GBCAs but does not cite any scientific studies confirming any causal link between trace amounts of retained gadolinium following the clinical administration of a GBCA and any clinical consequences, including "GDD"—because none exist. Indeed, no such "disease" has been accepted by FDA or the relevant medical community. To the contrary, they have concluded there is no evidence of causation between trace amounts of retained gadolinium and any clinical harm. Thus, Plaintiff cannot establish that Omniscan was the actual or proximate cause of Plaintiff's alleged injuries.

Moreover, Plaintiff's breach of express warranty claim fails because she does not comply with New Jersey's pre-suit notice requirement for warranty claims. Plaintiff also does not identify who made what affirmations or when in support of her express warranty claim.

Further, most of Plaintiff's Amended Complaint includes conclusory statements alleged against all Defendants, not GEHC specifically. As a result, Plaintiff's claims fall short of the pleading standard set forth in Federal Rule of Civil Procedure 8(a), *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007) and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009).

Finally, Plaintiff's claims are barred by the statute of limitations. Plaintiff was aware of gadolinium retention at least by January 2015, yet did not bring suit

against any parties for her alleged injuries until over four years later—well outside the two-year statute of limitations allowed by New Jersey law.

STANDARD OF REVIEW

In considering a motion to dismiss under Rule 12(b)(6), the Court must accept all well-pleaded facts as true, viewing them in the light most favorable to the plaintiff. *See Iqbal*, 556 U.S. at 678. A pleading that offers "labels and conclusions" or "a formulaic recitation of the elements of a cause of action will not do." *Id.* at 678 (quoting *Twombly*, 550 U.S. at 545).

"Factual allegations must be enough to raise a right to relief above the speculative level on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Twombly*, 550 U.S. at 555 (internal citations omitted). The claims must be plausible, rather than conceivable. *Id*. at 570. Probability is not required, but "sheer possibility" is not enough. *Iqbal*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 557.) "[B]are assertions" without any factual underpinning "are conclusory and not entitled to be assumed true." *Iqbal*, 556 U.S. at 681. Moreover, courts "are not bound to accept as true a legal conclusion couched as a factual allegation." *Id.* at 678. Indeed, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.*

Federal Rule of Civil Procedure 8(a)(2) requires a short and plain statement of the claim showing that the pleader is entitled to relief. In a case with multiple

defendants, a plaintiff must "specify which defendants performed which acts" which "is not satisfied where a complaint provide[s] only conclusory allegations against Defendants as a group." *Zuniga v. Amer. Home Mortgage*, No. 14-cv-2973(KM), 2016 WL 6647932, at *3-4 (D.N.J. Nov. 8, 2016) (internal citations omitted).

ARGUMENT

I. PLAINTIFF'S FAILURE-TO-WARN CLAIM IS PREEMPTED BY FEDERAL LAW

Plaintiff fails to state a failure-to-warn claim that is not preempted by federal law. To establish an inadequate warning claim regarding a prescription drug under NJPLA, a plaintiff must show that the product does not contain an adequate warning or instruction. A warning is adequate if it is "one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product." *Tafaro v. Six Flags Great Adventure, LLC*, No. 17-5607(FLW)(LHG), 2018 WL 1535289, at *10 (D.N.J. Mar. 29, 2018) (internal citations omitted).

Here, Plaintiff alleges that Defendants failed to adequately warn that gadolinium is retained following administration of Omniscan and that "gadolinium retention can result not only in NSF but also in NSF-like injuries on a spectrum leading up to NSF, as characterized by the injuries set forth herein and often

referred to as 'gadolinium deposition disease' or 'gadolinium toxicity' generally." Am. Compl. ¶¶ 88, 174(i).

As an initial matter, the label has never stated Omniscan™ is cleared 100% from the body after administration. Rather, the label stated:

> Gadodiamide is eliminated primarily in the urine with 95.4 ± 5.5% (mean ± SD) of the administered dose eliminated by 24 hours. The renal and plasma clearance rates of gadodiamide are nearly identical (1.7 and 1.8 mL/min/kg, respectively), and are similar to that of substances excreted primarily by glomerular filtration.

(*See* Certification of Debra M. Albanese dated September 17, 2019 ("Albanese Cert.") at ¶ 6, Ex. E ¶ 12.3.) In other words, the label at the time of Plaintiff's administrations of Omniscan™ stated that 90-99% of the product would be eliminated from her body within 24 hours, necessarily indicating that 1%-10% was not eliminated immediately.

Further, as shown below, Plaintiff's claim that GEHC should have warned of any clinical harm resulting from retained gadolinium is preempted.

A. FDA Studied Gadolinium Retention and Required Revised Labeling in April 2018 that Contradicts Plaintiff's Inadequate Warning Claim

The warning Plaintiff claims GEHC should have given her doctors when she received Omniscan in 2012, 2013, and 2016—on "the dangers of linear GBCAs"—is directly contrary to the warning approved and mandated in April 2018 by FDA for Omniscan, and all GBCAs. *See* Am. Compl. ¶ 172. Specifically, FDA's 2018

warning requires the labeling for all GBCA's (both the allegedly defective linear GBCA and the allegedly safer alternative macrocyclic GBCA) to state the following:

> **5.4 Gadolinium Retention**
>
> Gadolinium is **retained** for months or years in several organs. The highest concentrations (nanomoles per gram of tissue) have been identified in the bone, followed by other organs (e.g. brain, skin, kidney, liver, and spleen). The duration of retention also varies by tissue and is longest in bone. Linear GBCAs cause more retention than macrocyclic GBCAs. At equivalent doses, gadolinium retention varies among the linear agents with Omniscan (gadodiamide) and Optimark (gadoversetamide) causing greater retention than other linear agents [Eovist (gadoxetate disodium), Magnevist (gadopentetate dimeglumine), MultiHance (gadobenate dimeglumine)]. Retention is lowest and similar among the macrocyclic GBCAs [Dotarem (gadoterate meglumine), Gadavist (gadobutrol), ProHance (gadoteridol)].
>
> **Consequences of gadolinium retention in the brain have not been established**. Pathologic and clinical consequences of GBCA administration and retention in skin and other organs have been established in patients with impaired renal function *[see Warnings and Precautions (5.2)]*. There are rare reports of pathologic skin changes in patients with normal renal function. Adverse events involving multiple organ systems have been reported **in patients with normal renal function without an established causal link to gadolinium retention** *[see Adverse Reactions (6.3)]*.
>
> While **clinical consequences of gadolinium retention have not been established in patients with normal renal function**, certain patients might be at higher risk. These include patients requiring multiple lifetime doses, pregnant and pediatric patients [*see Use in Specific Populations (8.1, 8.4)*], and patients with inflammatory conditions. Consider the retention characteristics of the agent when choosing a GBCA for these patients. Minimize repetitive GBCA imaging studies, particularly closely spaced studies, when possible.

(*See* Albanese Cert. at ¶ 2, Ex. A (U.S. Prescribing Information for Omniscan § 5.3 (approved April 2018)) (emphasis added).)[2] FDA's issuance in April 2018 of new "class labeling" applies to all linear and macrocyclic GBCA agents marketed in the United States. And it explicitly states FDA's conclusion that no "causal link" nor any "clinical consequences" of gadolinium retention have been established in patients with normal renal function like Plaintiff.

FDA's conclusion came after months of intense and specific study by FDA. In fact, FDA convened a panel of more than a dozen medical and scientific experts to advise the agency on any consequences of this "retention" (FDA's Magnetic Imaging Drugs Advisory Committee, or "MIDAC"), and the broader medical and scientific community published scores of studies and papers on the phenomenon of retention and the absence, to date, of any evidence that the retention causes "GDD" or any other adverse health effects.

More specifically, the new April 2018 FDA warning language, expressly disclaiming precisely the "causal relationship" that Plaintiff claims Defendants were required to provide in 2012, 2013, or 2016 in order to avoid state tort liability, came after:

[2] "When deciding a motion to dismiss, a court may consider facts appropriate for judicial notice without converting the motion into a motion for summary judgment." *Clements v. Sanofi-Aventis, U.S., Inc.*, 111 F. Supp. 3d 586, 596 (D.N.J. 2015).

- FDA issued a Drug Safety Communication on **July 27, 2015**, (i) acknowledging discovery of brain deposits of gadolinium, (ii) stating that "it is **unknown** whether these gadolinium deposits are harmful or can lead to adverse health effects," (iii) describing the agency's further study "to determine **if** there are any potential adverse health effects," and (iv) explicitly stating that "[b]ased on the need for additional information, at this time, we are **not** requiring manufacturers to make changes to the labels of GBCA products." (Albanese Cert. at ¶ 3, Ex. B (emphasis added).)

- FDA's Drug Safety Communication further (i) referred to the medical literature describing gadolinium deposits, (ii) described the agency's ongoing and further research efforts to "investigat[e] the risk of brain deposits," (iii) explicitly stated that "[i]t is **unknown** whether these gadolinium deposits are harmful or can lead to adverse health effects," (iv) stated that "[b]ased on the need for additional information, at this time, we are **not** requiring manufacturers to make label changes to the labels of GBCA products," and (v) stated that, although "recent studies . . . have confirmed that gadolinium can **remain** in the brain, even in individuals with normal kidney function," . . . [a]vailable information does **not** identify **any** adverse health **effects**." (*Id.* (emphasis added).)

- In **September 2017**, numerous FDA officials, physicians and scientists, together with 15 outside physicians and scientists comprising the agency's Medical Imaging Drugs Advisory Committee (MIDAC), convened a meeting and public hearing on the subject of "the safety of gadolinium retention in the brain and other organs." (Albanese Cert. at ¶ 4, Ex. C (Transcript, Medical Imaging Drugs Advisory Committee (MIDAC) at 2-9, 25 (Sept. 8, 2017)).) That public meeting included extensive presentations by FDA scientists, industry representatives, as well as experts associated with Plaintiffs in the current GBCA litigation such as Dr. Richard Semelka (*id.* at 300 et seq (Semelka)). That meeting included specific discussion of the claimed effect of "Gadolinium Deposition Disease (GDD)" that Plaintiff claims to have suffered for lack of adequate warnings. (*Id.* at 293, 301, 304.) That FDA/MIDAC meeting also included in its afternoon session oral testimony from members of the public, including independent academics, patient advocates and a lawyer representing a "GDD" claimant. (*Id.* at 225 et seq.) The meeting

concluded with extensive discussion and voting on specific questions put to the MIDAC by FDA, including most pertinently, "[I]s there evidence of a **causal relationship** between symptoms and signs in patients with normal renal function now and gad[olinium] retention?" (*Id.* at 336.) On that question, the MIDAC panel members' votes (*id.* at 336-355) expressed "uniformity that there is **no evidence of a causal relationship** between the symptoms and signs in patients with normal renal function and the retention of gadolinium." (*Id.* at 355.)

- On December 19, 2017, FDA issued a third Drug Safety Communication, which acknowledged the discovery that "[a]fter being administered, GBCAs are mostly eliminated from the body through the kidneys[,] [h]owever, trace amounts of gadolinium may stay in the body long-term." (Albanese Cert. at ¶ 5, Ex. D at 2.) FDA then addressed the "causal relationship" Plaintiff claims GEHC should warned of prior to 2017. FDA stated:

    - "Gadolinium retention has **not** been directly linked to adverse health effects in patients with normal kidney function." (*Id.* at 2.)

    - "To date, the only known adverse health effect related to gadolinium retention is a rare condition called nephrogenic systemic fibrosis (NSF) that occurs in a small subgroup of patients with pre-existing kidney failure. We have also received reports of adverse events involving multiple organ systems in patients with normal kidney function. A **causal association between these adverse events and gadolinium retention could not be established**." (*Id.* at 3.)

The revised April 2018 labeling and its new warning language, described above, was approved by FDA and issued after these years of FDA research, FDA meetings, advisory panels, and review of the available data by the agency. Indeed, Plaintiff cites to this research and FDA meetings in her Complaint, while ignoring the conclusions of these studies and meetings. *See* Am. Compl. ¶¶ 109-134. As

shown above, the FDA-approved 2018 labeling expressly disclaims precisely the same causal relationship warning for patients with normal renal function that Plaintiff's allegations claim GE Healthcare was required to issue to avoid state tort law liability.

Indeed, Plaintiff's alleged "safer alternative," macrocyclic agents, carries this same warning, issued long after Plaintiff's doctors used Omniscan to enhance her MRI images. *See id.* at ¶ 193.

B. Plaintiff's Inadequate-Warning Claim Is Preempted Because It Conflicts with GEHC's Obligations to FDA Under Federal Law

Under federal conflict preemption doctrine, pursuant to the Supremacy Clause of the United States Constitution, "state law that conflicts with federal law is without effect." U.S.C.A. Const. Art. VI cl. 2. State laws can conflict with federal law because either (i) the state law "prevent[s] or frustrate[s] the accomplishment of a federal objective," or (ii) the state law "make[s] it impossible for private parties to comply with both state and federal law." In each case, the state law is "nullified by the Supremacy Clause." *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 873 (2000). "State laws" that may impermissibly conflict with federal law and thus be preempted include state-law failure-to-warn claims alleging, as here, that a product "should have included additional, or more clearly stated, warnings." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 524 (1992).

In the context of conflicts between pharmaceutical products liability claims and FDA labeling regulations, "clear evidence that the FDA would not have approved a change to the drug's label pre-empts a claim, grounded in state law, that a drug manufacturer failed to warn consumers of the change-related risks associated with using the drug." *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S.Ct. 1668, 1672 (2019) (citing *Wyeth v. Levine*, 555 U.S. 555, 571 (2009)). Thus an inadequate-warning claim is preempted if there is clear evidence FDA would have not have approved the warning that a plaintiff alleges was required under state tort law. Whether there is clear evidence preempting a claim is a question for the Court, not a jury. *Albrecht*, 139 S.Ct. at 1679. In answering the question of "clear evidence," "the judge must simply ask himself or herself whether the relevant federal and state laws 'irreconcilably conflict.'" *Id.* at 1679 (citation omitted).

A separate, similar conflict can occur where the plaintiff fails to allege a sufficient basis for a manufacturer to have unilaterally changed its warnings pursuant to the FDA's "changes being effected" or "CBE" regulation. The Supreme Court in *Albrecht* recently summarized the "CBE" regulation and label-change process as follows:

> "[F]ederal law—the FDA's CBE regulation—permits drug manufacturers to change a label to "reflect newly acquired information" if the changes "add or strengthen a ... warning" for which there is "***evidence of a causal association***," without prior

> approval from the FDA. 21 C.F.R. § 314.70(c)(6)(iii)(A). Of course, the FDA reviews CBE submissions and can reject label changes even after the manufacturer has made them. See §§ 314.70(c)(6), (7). And ***manufacturers cannot propose a change that is not based on reasonable evidence***.
> § 314.70(c)(6)(iii)(A).

Id. (emphasis added).

The U.S. Court of Appeals for the Second Circuit recently outlined these two species of conflict preemption in the pharmaceutical context—(1) clear evidence FDA would not approve the warning plaintiff says was required, or, (2) inability of the defendant lawfully to change the label under the CBE regulation—as follows:

> "Thus, to state a claim for failure-to warn that is not preempted by the FDCA, a plaintiff must plead 'a labeling deficiency that [Defendants] could have corrected using the CBE regulation.' (citations omitted.) If the plaintiff meets that standard, the burden shifts to the party asserting a preemption defense to demonstrate that there is 'clear evidence that the FDA would not have approved a change' to the [prescription drug's] label."

Gibbons v. Bristol-Myers Squibb Co., 919 F.3d 699, 708 (2d Cir. 2019) (dismissing complaints that lacked sufficient factual allegations to state a claim that is not preempted).

Plaintiff's Amended Complaint fails to state a failure-to-warn claim that is not preempted by federal law under either theory, and therefore that claim must be dismissed.

1. Plaintiff Fails to Plead Scientific Evidence of A Causal Association Between Omniscan and "GDD" That Would Allow GEHC to Change the Label On Its Own

Although Plaintiff references numerous studies regarding gadolinium retention in her Complaint, Plaintiff does not and cannot allege that any of these studies found a causal association between Omniscan and "GDD"—the causal association of which she claims GEHC failed to warn her doctors sometime before 2012, 2013, and 2016. In a recent GBCA case like this one, *McGrath v. Bayer HealthCare Pharms.*, No. 18 CV 2134 (RJD)(VMS), 2019 WL 2582530, at *1 (E.D.N.Y. June 24, 2019), the district court found preempted and dismissed a plaintiff's failure-to-warn claim alleging that she and her providers had been left wrongfully unwarned of the alleged risk of "fibrosis in organs, bone, and skin as well as muscle pain, muscle weakness, brain fog and other injuries"—i.e., "GDD"—allegedly associated with use of GBCAs. In that case, the plaintiff provided similar scientific evidence regarding her claims, and the Court analyzed that evidence. In doing so, the Court concluded the plaintiff's complaint failed to adequately plead the existence of reasonable evidence for a "causal association" that would have permitted the manufacturer to unilaterally change labeling pursuant to the CBE regulation. *Id.* at *5.

Here, similar to *McGrath*, Plaintiff has failed to allege any "reasonable evidence" of any "causal association" between use of GBCAs and "GDD" that

would have supplied GEHC with the requisite basis to unilaterally change its labeling pursuant to the CBE regulation at the time(s) she alleges she used the product(s)—i.e., before 2012, 2013, and 2016. Further, as in *McGrath*, Plaintiff's Amended Complaint is replete with references to gadolinium retention, but offers no reasonable or plausible evidence that she could sustain a claim that GEHC was required to warn of a causal relationship between any such retention and the effects she claims to have experienced. *See id*. Plaintiff's Amended Complaint does not refer to a single study, medical or scientific organization, or pharmaceutical regulatory agency anywhere in the world that has concluded, stated, or even suggested that any such "causal relationship" between GBCAs and "GDD" has been established, or even that any such relationship is supported by reasonable scientific evidence—because there are none.

As pleaded in the Amended Complaint, like the *McGrath* plaintiff, Plaintiff has failed to plead a claim that is not preempted by the CBE regulation, which requires "reasonable evidence" for GEHC to have made any such change prior to 2012, 2013, or 2016 (or to this day) without running afoul of the reasonable evidence requirement of the CBE regulation.

2. Clear Evidence Confirms FDA Would Have Rejected Plaintiff's Warning of a Causal Association Between Omniscan and "GDD"

Plaintiff's Amended Complaint fails to allege a non-pre-empted failure-to-warn claim for a second, separate reason. This is the rare case where there is not

only clear evidence, but, indeed, no question whatsoever, that FDA would not have approved a warning that retained gadolinium can "result in" injuries such as "GDD" at the time Plaintiff received Omniscan (some time prior to 2012). The clarity is supplied by FDA's multiple statements to the medical profession in the several years leading up to 2016 and FDA's ultimate issuance in April 2018 of revised warnings about gadolinium retention. All of these statements, outlined and quoted above, expressly disclaim that any causal relationship between retained gadolinium and any adverse effect in patients with normal renal function has ever been established. Thus, the very "causal relationship" Plaintiff claims was required to be in the warnings under state law, is a causal relationship that, after her use of the product, FDA has expressly disclaimed. It is difficult to imagine stronger "clear evidence" that FDA would have disallowed a "GDD" warning some years ago when Plaintiff claims she and her providers should have received such a warning. Plaintiff has alleged no facts or circumstances that, if true, would plausibly explain why or how FDA would have approved a warning about a causal relationship to GDD in 2012, 2013, or 2016, and yet have required manufacturers to disseminate warnings that expressly disclaim any such causal relationship, in 2018, after her last alleged use. Because she has failed to adequately plead a non-preempted failure-to-warn claim, her claim should be dismissed.

II. ALL OF PLAINTIFF'S CLAIMS FAIL BECAUSE PLAINTIFF DOES NOT COMPLY WITH STATE LAW OR FEDERAL PLEADING RULES

Plaintiff has not pled facts to support her claims of failure to warn, defective design, and breach of express warranty claims, and thus her Amended Complaint must be dismissed.

A. Plaintiff Cannot Show that GEHC Caused Her Injuries As Required Under the NJPLA

Under the NJPLA, there are three causes of actions available: manufacturing defect, failure to warn, or design defect. *Nelson v. Biogen Idec Inc.*, No. 12-7317, 2013 WL 1700918, at *2 (D.N.J. Apr. 19, 2013); N.J.S.A. § 2A:58C-2. To establish a prima facie case under any theory of the NJPLA, "a plaintiff must show that the defendant manufactured the product, that a reasonably foreseeable user was injured, that the product was defective, that the defect existed when it left the defendant's control, and that the defect was the actual and proximate cause of the plaintiff's injury." *Thompson v. Harrah's Atl. City Holding, Inc.*, No. 14-2397, 2018 WL 1535206, at *3 (D.N.J. Mar. 29, 2018) (citing *Worrell v. Elliott & Frantz*, 799 F. Supp. 2d 343, 350 (D.N.J. 2011)).

Plaintiff does not assert any facts to support causation for her failure to warn, manufacturing defect, and design defect claims. To establish Plaintiff's injury, she "must show that the defendant's act or omission was" both "the factual, or 'but for,' cause of the injury" and "a proximate cause of the injury." *Cruz-*

Mendez v. ISU/Ins. Servs., 722 A.2d 515, 524 (N.J. 1999). But Plaintiff fails to allege facts to show that Omniscan was the "but for" or the proximate cause of her alleged injuries. For example, Plaintiff alleges that because of her exposure to "Defendants' GBCAs, Plaintiff has retained gadolinium, and as a direct and proximate result of that retained gadolinium, suffers from gadolinium toxicity, or Gadolinium Deposition Disease (GDD)." Am. Compl. ¶ 166. But in the Amended Complaint, Plaintiff claims: (1) she received three different GBCAs over a ten-year period, (2) she has developed GDD, (which is not recognized by the scientific community, including FDA) at some undefined time, and (3) studies have observed that gadolinium can be retained in the body. *See id.* ¶¶ 109-134. Gadolinium retention alone is not an injury. *See Sinclair v. Merck & Co.*, 948 A.2d 587, 595 (N.J. 2008) (holding that plaintiffs' potential latent injuries after exposure to a pharmaceutical product withdrawn from the market "cannot satisfy the definition of harm to state a product liability claim under the [NJ]PLA."); *Koronthaly v. L'Oreal USA, Inc.*, 374 F. App'x 257, 259 (3d Cir. 2010) (finding plaintiff failed to state an injury-in-fact because lipsticks contained lead partly because plaintiff suffered no adverse health effects). Further, Plaintiff does not and cannot allege any disease caused by Omniscan for which Plaintiff is at risk given her normal renal function. Am. Compl. ¶ 165. Rather, because GBCAs are associated with a

distinct disease in a distinct population that does not include Plaintiff, she attempts to bootstrap claims here without any plausible factual basis.

Plaintiff also alleges that GEHC made "misrepresentations and omissions" in promoting Omniscan and, yet, does not provide any factual allegations to show how Omniscan was marketed to Plaintiff, what her healthcare providers said about the product, or the risks she was aware of. *See id.* at ¶ 214.

She does not link any defect in the manufacture, design, or warnings that accompanied Omniscan with her own injuries. Plaintiff further suggests that macrocyclic GBCAs are a safer alternative, without providing any facts to show how a macrocyclic GBCA would have not caused her alleged symptoms. *Id.* at ¶ 109. Plaintiff also does not state the risks of using macrocyclic agents, which is critical, because the labeling required by FDA for Omniscan is identical to labeling required for macrocyclic GBCAs. Indeed, the scientific evidence cited by Plaintiff confirms that both linear and macrocyclic GBCAs are retained in trace amounts following administration. Because Plaintiff's allegations amount to no more than conclusory allegations, her NJPLA claims must be dismissed.

B. Plaintiff's Failure-to-Warn Claim Also Does Not Overcome the Presumption that Omniscan's Warning is Adequate

The NJPLA provides that FDA-approved warnings for pharmaceutical products are entitled to a "super-presumption" such that the warning will be found adequate as a matter of law, except in 'rare' cases. *Kendall v. Hoffman-La Roche,*

Inc., 36 A.3d 541, 554-55 (N.J. 2012); *see also In re Accutane Litig.*, 194 A.3d 503, 531 (N.J. 2018) ("The presumption of adequacy protects manufacturers from unmeritorious lawsuits."). Specifically, there are three ways to overcome the presumption. First, a plaintiff must show that there was "deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects." *Id.* at 531 (citing *Perez v. Wyeth Labs, Inc.*, 734 A.2d 1245, 1259 (N.J. 1999)). Second, a plaintiff can overcome the presumption if he or she can demonstrate an "economically-driven manipulation of the post-market regulatory process." *Id.* (internal citation omitted). And the third pathway to overcoming the presumption is "if a plaintiff can prove by clear and convincing evidence that a manufacturer knew or should have known in the postmarketing phase that the drug warnings were inadequate based on the label warning updating requirements in 21 C.F.R. § 201.57(c), 21 C.F.R. § 314.70(c), or any other pertinent federal regulation." *Id.*

As an initial matter, Plaintiff concedes that GEHC's labels are FDA-approved. *See* Am. Compl. ¶¶ 104, 128, 155. Plaintiff also provides no facts to support any of the three methods of overcoming the super-presumption of the adequacy of GEHC's label. Not only does Plaintiff fail to allege any facts showing GEHC deliberately concealed the purported harmful effects of Omniscan in individuals with normal renal function, Plaintiff affirmatively states that studies showed gadolinium retention in patients with normal renal function as early as

2004—eight years before Plaintiff first received Omniscan. Further, Plaintiff does not (and cannot) provide any evidence that GEHC engaged in economically driven manipulation of the post-market regulatory process.

Plaintiff also cannot allege that GEHC knew or should have known in the post-marketing phase that Omniscan's drug warnings were inadequate based on label warning updating requirements in 21 C.F.R. § 201.57(c), 21 C.F.R. § 314.70(c), or any other pertinent federal regulation. As discussed in Section I, the FDA actively engaged in the post-marketing phase of Omniscan, and GEHC has followed all recommendations made by FDA. Thus, Plaintiff cannot overcome New Jersey's super-presumption of adequacy, and Plaintiff's failure to warn claim must be dismissed as it fails on this basis as well.

C. Plaintiff's Breach of Express Warranty Claims Fail Because Plaintiff's Claim Does Not Comply with New Jersey Law

As a pre-requisite to filing a breach of express warranty claim, New Jersey law requires that a party provide pre-suit notice of a breach of express warranty or implied warranty claim. *See* N.J.S.A. § 12A:2-607 ("Where a tender has been accepted….the buyer must within a reasonable time after [s]he discovers or should have discovered any breach notify the seller of breach or be barred from any remedy"). The pre-suit notice must be provided before suit is filed. *See Hammer v. Vital Pharms., Inc.*, No. 11-4124, 2012 WL 1018842, at *10-11 (D.N.J. Mar. 26, 2012) (finding the "lack of allegations involving pre-litigation notice" "fatal" to

plaintiff's breach of express warranty and implied warranty claims). Here, Plaintiff did not provide the requisite notice for her warranty claims. Thus, Count III of Plaintiff's Amended Complaint fails on this basis alone.

Further, Plaintiff's express warranty claim does not identify any statement made by GEHC, a necessary element of the claim. Under New Jersey law, a claim for breach of express warranty has three elements: "(1) that Defendant made an affirmation, promise or description about the product; (2) that this affirmation, promise or description became part of the basis of the bargain for the product; and (3) that the product ultimately did not conform to the affirmation, promise, or deception." *Snyder v. Farnam Companies, Inc.*, 792 F. Supp. 2d 712, 721 (D.N.J. 2011).

Here, Plaintiff does not allege that "any identifiable, unapproved statements" were made to Plaintiff or her healthcare providers regarding the use of GBCAs. *Clements*, 111 F. Supp. 3d at 602. "Who said what to whom, where, when, and how, are left unexpressed." *Id*. This Court in *Clements* rejected a similar express warranty claim because it was "a formulaic recitation of the elements of a cause of action." *Id.* (citing *Twombly*, 550 U.S. at 556.) This Court should do the same here.

D. Plaintiff Fails to Provide Sufficient Facts to Assert Any Claims Against GEHC Under Rule 8(a)

Despite amending her complaint, Plaintiff's 224-paragraph Amended Complaint includes only one unique allegation specific to Plaintiff's use of

Omniscan: that Plaintiff received Omniscan on December 18, 2012; July 16, 2013; and on March 24, 2016. Am. Compl. ¶¶ 22, 164. Other than jurisdictional allegations, Plaintiff makes only general allegations against all 11 defendants named in this case. This is improper.

Pleadings that refer generally to "defendants" as a group without distinction are routinely dismissed because the plaintiff failed to satisfy the plausibility standard of Rule 8. *Transportation Insurance Co. v. Am. Harvest Baking Co., Inc.*, No. CV 15-663 (NLH/AMD), 2015 WL 9049273, at *8 (D.N.J. Dec. 16, 2015); *Galicki v. New Jersey*, No. 14-169 (JLL), 2015 WL 3970297, at *2 (D.N.J. June 29, 2015) ("Plaintiffs provide only conclusory allegations against Defendants as a group, failing to allege the personal involvement of any Defendant as is required.") "Without belaboring the point, group pleading of the kind practiced in the instant Complaint undermines the notice pleading regime of Rule 8 and is a technique best relegated to a bygone era, if in fact it was ever acceptable then." *Japhet v. Francis E. Parker Mem'l Home, Inc.*, No. 14-01206 (SRC), 2014 WL 3809173, at *2 (D.N.J. July 31, 2014).

Excluding Plaintiff's jurisdiction and venue allegations, nearly every paragraph of the Amended Complaint is made against all Defendants. *See generally* Am. Compl. ¶¶ 87-155. Plaintiff does not "specify which defendants performed which acts" or explain the "personal involvement" of GEHC in causing

her alleged injuries. *Zuniga*, 2016 WL 6647932, at *3; *Galicki*, 2015 WL 3970297, at *2. Thus, Plaintiff's Amended Complaint should be dismissed for failure to comply with Rule 8(a).

III. PLAINTIFF'S CLAIMS ARE BARRED BY THE TWO-YEAR STATUTE OF LIMITATIONS PERIOD

Plaintiff filed suit on April 24, 2019. *See* Compl. Under New Jersey law, the statute of limitations for a products liability claim is two years. *Boldman v. Wal-Mart Stores, Inc.*, No. 16-4, 2016 WL 4418219, at *2 (D.N.J. Aug. 17, 2016). Thus, Plaintiff's claim is barred if she believed that she had injuries related to gadolinium before April 24, 2017. *See* N.J.S.A. § 2A:14-2; *see also Yarchak v. Trek Bicycle Corp.*, 208 F. Supp. 2d 470, 478-79 (D.N.J. 2002).

New Jersey's discovery rule states a claim does not accrue until the plaintiff "discovers, or by any exercise of reasonable diligence and intelligence should have discovered that he may have a basis for an actionable claim." *Catena v. Raytheon Co.*, 145 A.3d 1085, 1090 (N.J. Super. Ct. App. Div. 2016). In determining whether the discovery rule should apply, the relevant question is "when plaintiff was aware, or reasonably should have been aware of the existence of a *state of facts* that may equate in the law with the cause of action." *Yarchak*, 208 F. Supp. 2d at 479 (internal quotation marks omitted).

Plaintiff was aware she had a potential claim related to gadolinium by early 2015. On January 26, 2015, Plaintiff's husband Larry Gremo created a

"GoFundMe" page to raise money for alleged treatment of "heavy metal poisoning" and "[c]helation" treatment. *See* Larry Gremo, *Fundraiser by Larry Gremo*, GoFundMe, https://www.gofundme.com/kvopu4 (last visited Sept. 10, 2019). Similarly, Plaintiff makes numerous references in her Amended Complaint to "chelation" and her alleged theory that Defendants' GBCAs harmed her due to "de-chelation." *See* Am. Compl. ¶¶ 87, 194-95.

Accordingly, Plaintiff was aware of her alleged gadolinium toxicity at least as early as January 2015, when her husband created the GoFundMe page for her chelation therapy. Plaintiff's product liability claims began to run in January 2015, at the latest. Plaintiff's claims were therefore barred by the time she filed her complaint, and this Court should dismiss Plaintiff's claims with prejudice.

CONCLUSION

Plaintiff's claims are not supported by any well-pleaded facts, as Plaintiff instead relies primarily on conclusory allegations. To the extent Plaintiff provides some detail regarding the alleged inadequate warnings for Omniscan, these allegations demonstrate her warnings claim is preempted by federal law. Further, Plaintiff's complaint was filed over four years after she was aware of her claim, demonstrating her claims are time-barred. GEHC therefore respectfully requests that this Court dismiss Plaintiff's claims pursuant to Rule 8(a) and Rule 12(b)(6).

Dated: September 17, 2019.

Respectfully submitted,

s/ Debra M. Albanese

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